

## **What Can One Reasonably Expect From Regulatory Peer Review?**

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Before embarking on the complexities of this question, it is important to remind ourselves of the boundaries of the answers. There are certain things we know we should not expect from peer review and certain things we know we should demand.

Minimally, a peer review process should genuinely be attempting to improve on intellectual substance, whether that is the document under review or future similar regulatory efforts. For example, the review could help to improve the document by making its presuppositions more explicit, or by helping it make better use of available data. If, on the other hand, the reviewers find that the document is adequate given the currently available research, then the review can help guide further research so that future documents will have a more solid basis. It might be that there is nothing to improve on in the document; if so, great. But at the outset, it should be assumed that there is, and the review should be structured to find it. In other words, peer review aimed at merely cosmetic approval (or, more rarely, disapproval) should not be acceptable under any circumstances. To accept such peer review in some instances will only undermine whatever credibility peer review currently affords regulatory efforts.

So that is the lower bound. What is the higher? What peer review cannot do is guarantee the truth of the claims in the document under review. We don't have any processes that guarantee truth. Peer reviews for journals don't guarantee truth; they enforce standards for a discipline on whether a piece of work was executed with sufficient rigor to be worth further discussion and debate. (I.e.- Does the piece contribute to the ongoing disciplinary debate?) Peer review for grant proposals don't guarantee that truth will be discovered; they suggest which proposals look the most promising for a field's development. (I.e.- Will the research likely produce results that will contribute to the ongoing disciplinary development?) Similarly with regulatory peer review, we should not expect the review process to ensure us of the truth of the statements made in the document, or the absolute accuracy of the methods. Regulatory peer review is usually more extensive than journal peer review, and often more extensive than funding peer review. We expect peer reviewed regulatory documents to do more than simply contribute the ongoing discussion; they are often more authoritative than a journal article. Nevertheless, we cannot expect regulatory peer review to ensure truth; there are no processes for that.

In between the lower bound of making substantive contributions and the upper bound of guaranteeing truth, there is a wide open space for varying expectations. In my closing comments for the day, I will discuss the tensions among the various expectations, practical limitations, and procedural issues that shape a regulatory peer review.